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PROPERTY RIGHTS IN LIVING MATTER: IS NEW LAW REQUIRED?

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I. INTRODUCTION

In non-technical parlance, biotechnology means the manipulation of the basic substance of living matter and its modification to achieve the purposes of the manipulator. A Congressional Committee has defined biotechnology, for example, as “(a)ny technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals or to develop microorganisms for specific uses.”¹ These techniques include disparate levels of sophistication, ranging from the selective breeding of animals to the manipulation and alteration at cellular and molecular levels of hybridomas, RNA, DNA, vectors, plasmids, monoclonal antibodies, vaccines and altered microorganisms.

Researchers employing these techniques within the broadly defined field of biotechnology may as likely be working toward a cure for AIDS, creating a genetically modified research animal particularly susceptible to cancer, or producing a steer or chicken with desired characteristics previously available only through selective breeding programs. As asserted before Congress, biotechnology represents 1988 revenues of \$762 million and export sales of \$215 million, figures which are nearly double the revenues for 1987 and quadruple those for 1986.² The growth of the industry has been projected to be \$40 billion within the next ten years, with research and development comprising a significant portion of investment for the industry.³ As a new field of scientific research and development, biotechnology has spawned its own language

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1. Subcomm. on Investigations and Oversight, as Transmitted to the Comm. on Science and Technology, 99th Cong., 2d Sess., REPORT ON ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE 1 n.1 (Comm. Print 1986).

2. Statement of the Industrial Biotechnology Association in Support of the Biotechnology Patent Protection Act (H.R. 3957) to the Subcomm. on Courts, Intellectual Property, and the Administration of Justice of the House Judiciary Comm. 1-2 (Sept. 25, 1990).

3. *Id.*

born of concepts distinct from the well-known mechanical arts. This factor, combined with the significant commercial success of technology relating to living matter that has been achieved within the last few decades, has prompted strong pressure to create legislation tailored to the new technology.

In that vein, some practitioners in the arts of biotechnology contend that fundamental changes are required to adapt patent law to the needs of this rapidly growing and heavily research and development intensive industry. Within the last few years a number of bills have been presented in Congress to address problems perceived as unique to biotechnological inventions, including the Patent Competitiveness and Technological Innovation Act of 1990⁴ which proposed, in part, to amend provisions relating to infringement and patentability.

No doubt, the unique circumstance of inventions that self-replicate and the difficulty of distinguishing what was made by man from what existed in nature are peculiar to the law of patenting living things. History tells us, however, that the well-established and basic premises of patent law that have been responsive to other new and rapidly developing technologies unenvisioned even a short number of years ago, should be flexible enough to accommodate the new technologies relating to living matter.

The patent system has always been premised on the basic idea of encouraging innovation, an idea that is inherently flexible. So important was this idea to the framers of the Constitution that they charged Congress with promoting the "Progress of Science and useful Arts" by the grant of exclusive rights to writings and discoveries.⁵ This mandate does not provide any particular definition for the subject matter of such inventive discoveries, but Congress has interpreted it to include "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."⁶ These broad definitions are based, in substantial part, on patent legislation enacted as early as 1793.⁷ Few changes have been made to the basic character of the patent system since its constitutional birth, despite the significant technological advances in electronics, superconductivity, pharmaceuticals and polymer chemistry, and despite the early bases of biotechnology provided in the publication of Gregor Mendel's genetics studies in 1866.⁸ In the interest of maintaining a coherent system of patent law principles upon which future and presently unknown developments can predictably be built, the temptation must be avoided to create individualized patent laws for any new technology.

4. H.R. 5598, 101st Cong., 2d Sess., 136 CONG. REC. H7498 (1989).

5. U.S. CONST. art. I, § 8, cl. 8.

6. 35 U.S.C. § 101 (1988).

7. *See generally* W. BENNETT, THE AMERICAN PATENT SYSTEM 64-67 (1943) (history of American patent system).

8. G. MENDEL, EXPERIMENTS IN PLANT HYBRIDISATION (Harvard University Press 1950).

II. PATENTABILITY OF LIVING MATTER: A BRIEF HISTORY

Although it is often assumed that biotechnology is a modern development and that the Patent and Trademark Office only recently began considering "biotechnical" inventions, patents covering biotechnology developments have historic origins. For example, the patent issued to Louis Pasteur claimed a yeast.⁹ Other early patents claimed a vaccine in the form of an altered virus¹⁰ and a process for optimizing the efficiency of anaerobic bacteria.¹¹ In addition, patents were routinely granted on fermentation processes. All of these were issued without any fundamental change in the patent statutes or any serious dispute over the authority to issue patents that related to living matter.

The patentability of inventions using living matter was brought to high visibility when a scientist at General Electric Company, Ananda Chakrabarty, tried to obtain a patent for a strain of *Pseudomonas* that metabolized components of crude oil.¹² Chakrabarty's claims to the bacterium were rejected by a United States Patent and Trademark Office (PTO) examiner as being "products of nature" and "not patentable subject matter under 35 U.S.C. § 101."¹³ Chakrabarty appealed the rejection to the Patent Office Board of Appeals, which affirmed the rejection on the second ground.¹⁴

The issue of the per se patentability of microorganisms was presented to the Court of Customs and Patent Appeals in *Chakrabarty* and another earlier case, *In re Bergy*,¹⁵ which concerned a claim for a biologically pure culture of a bacterial strain capable of producing an antibiotic.

The Court of Customs and Patent Appeals reversed the PTO's rejection, in both *Bergy* and *Chakrabarty*, holding that "the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance" for the purposes of the patent law.¹⁶ *Bergy* and *Chakrabarty* were consolidated for reconsideration; the earlier judgments were reaffirmed and although certiorari was sought for both, it was ultimately *Chakrabarty* that placed the issue before the Supreme Court.¹⁷

In considering whether the claimed microorganism constituted a "manufacture" or "composition of matter" within section 101 of the Patent Act,¹⁸ the Court applied its earlier definition of "manufacture" as

9. U.S. Patent No. 141,072.

10. U.S. Patent No. 197,612.

11. U.S. Patent No. 634,423.

12. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

13. *Id.* at 306. The PTO reasoned that, since the passage of the 1930 Plant Patent Act "extended" patent protection to include some living material (asexually reproduced plants), Congress did not intend section 101 to cover any living material. *See id.*

14. *Id.*

15. 563 F.2d 1031 (C.C.P.A. 1977), *vacated*, *Parker v. Bergy*, 438 U.S. 902 (1978), *vacated & aff'd*, *Diamond v. Chakrabarty*, 444 U.S. 1028 (1980).

16. *Id.* at 1038.

17. *Chakrabarty*, 447 U.S. at 306-07.

18. 35 U.S.C. § 101 (1988).

"the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."¹⁹ Similarly, a composition of matter was construed to include "all composite articles, whether they be the results of chemical union, or of mechanical mixture."²⁰

Thus, in affirming the judgment of the Court of Customs and Patent Appeals, the Supreme Court acknowledged that section 101 was intended to "include anything under the sun that is made by man."²¹ Indeed, the Court stated that the *only* consideration relevant to a section 101 analysis is that the living thing results from human intervention and has a distinctive name, character and use.²²

Chakrabarty opened the door for the patenting of every kind of living matter. The PTO readily accepted the holding as permitting patent protection for bacteria, viruses, fungi and yeasts, human and animal cell lines. The PTO even extended section 101 to plants that fell within the scope of the Plant Variety Protection Act.²³ In a case decided nearly two years after *Hibberd*, it became clear that altered animals such as non-naturally occurring polyploid oysters were also considered to fall within the purview of section 101.²⁴ On April 12, 1988, the first patent issued on a mammal, claiming "a transgenic non-human mammal [preferably a rodent such as a mouse] all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence," known as the "oncomouse."²⁵

All this was accomplished without the necessity for any statutory changes to accommodate the new technology. Indeed, the use of deposits for the continued preservation of genetic materials and organisms is an example of how the industry took the necessary steps to fit itself into the established framework of laws.

Despite these accomplishments, we are now told by representatives on both sides of the patent fence that some fundamental patent law principles must be changed to accommodate biotechnical inventions. One side argues that the constitutional provision of exclusivity and the long history of repugnance for compulsory licenses must give way to a special exemption allowing free reproduction of patented animals. The other side argues that a new class of per se nonobviousness must be created, in contradiction of long-standing case law, obligating the PTO to grant patents automatically on processes previously recognized as obvious, provided only that an essential element used in that process is novel and unobvious. Before special exceptions are granted for any

19. 447 U.S. at 308 (quoting *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

20. *Id.* (quoting *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

21. *Id.* at 309 (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 5; H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6, *reprinted in* 1952 U.S. CODE CONG. & ADMIN. NEWS 2394, 2399).

22. *See id.* at 309-10.

23. *See Hibberd*, 227 U.S.P.Q. (BNA) 443 (PTO Bd. Pat. App. & Int'l. 1985).

24. *See Allen*, 2 U.S.P.Q.2d (BNA) 1425 (PTO Bd. Pat. App. & Int'l. 1987), *aff'd*, No. 87-1393 (Fed. Cir. Mar. 14, 1988).

25. U.S. Patent No. 4,736,866.

technical field, however, we should examine critically whether it is either wise or necessary to tinker with a body of principles that is basically sound and well-understood.

III. PROTECTING RIGHTS IN PROPAGATING LIFE FORMS

Particularly since the issuance of the "oncomouse" patent, the scientific and political communities have uniformly recognized that patenting life forms raises novel political, ethical, and legal issues inconceivable in inventions relating to non-living matter. One of the more troublesome issues relates to protection of the patent holder's rights when the invention is capable of propagation. In the case of microorganisms, propagation is usually a prerequisite to the practice of the invention. However, the use of transgenic animals for the purposes of the patented invention does not necessarily involve the propagation of these genetically altered animals.

A. *The Technology of Transgenic Animals*

Transgenic animals differ from animals of nature because they contain foreign DNA within their genetic blueprint, or genome, that has been introduced by man through recombinant DNA techniques. For example, "oncomice" have a mouse tumor gene, broadly known as an "oncogene," inserted into their genome, the expression of which is under the control of a gene sequence derived from a tumor-causing virus. The patent claims are broadly directed to non-human mammals having cells containing recombinant, activated oncogenes introduced into the mammal or its ancestor at an embryonic stage. The utility of the claimed animals is primarily in cancer research. Mammals containing genes of the type claimed are highly susceptible to cancer and therefore are ideal "test tubes" for testing suspected carcinogens or evaluating the efficacy of anti-cancer drugs. Transgenic animals could also be produced with other genetic deficiencies or modifications useful in the study of the causes of human diseases, and the search for their cures.

Transgenic techniques also permit the insertion into the genome of one species, gene sequences from another species. Such techniques provide an important new way to produce superior livestock without resort to conventional breeding programs. Moreover, these animals containing "foreign" gene sequences can be protected under the patent laws, whereas animals produced under selective breeding programs cannot.

Transgenic animals of the same line, that is, homozygous animals carrying the same inserted gene sequence, can be mated to produce offspring with the same genetic makeup. Consequently, a purchaser of a patented animal who acquires at least two transgenic animals of opposite sex acquires the capability of producing more animals of that line. The issue arises whether the purchaser of such patented animals also

acquires the right to produce more animals based on the ones obtained from the patent holder. Similar questions accompany the sale of plant seeds, microorganisms, and other living matter that can either self-replicate, or from which genetic material can be extracted and used by the purchaser to produce similarly modified variants.

B. *Propagation of Animals and Cell Cultures*

A pharmaceutical firm purchasing patented mice for the purposes of testing an antitumor drug might also use some of the mice for breeding, in order to maintain a line for use in further tests and in other experiments without resorting to the patent holder or his licensee. The purchaser may assert that the sale of patented animals by the patent holder exhausted the patent monopoly, thereby depriving the patent holder of the right to control or restrict subsequent use of the animals sold.

Precedent for that argument is *Adams v. Burke*,²⁶ in which the Court found that the sale of a patented invention by one authorized to sell it gives the purchaser an implied license to use or resell the invention without restriction.²⁷ Mechanical devices do not present a problem since they cannot inherently reproduce. However, in the case of a patented animal, or any other living matter whose inherent capabilities include reproduction, the question becomes difficult to resolve.

Statutory solutions to the reproduction question were provided in the Plant Patent Act²⁸ and the Plant Variety Protection Act of 1970.²⁹ The Plant Patent Act expressly provides that "[i]n the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced."³⁰

Similarly, the Plant Variety Protection Act provides that it is an act of infringement to:

- (3) sexually multiply the novel variety as a step in marketing (for growing purposes) the variety; or
- (4) use the novel variety in producing (as distinguished from developing) a hybrid or different variety therefrom; or
- (5) use seed which had been marked "Unauthorized Propagation Prohibited" or "Unauthorized Seed Multiplication Prohibited" or progeny thereof to propagate the novel variety; or
- (6) dispense the novel variety to another, in a form which can be propagated, without notice as to being a protected variety under which it was received.³¹

The issue of propagation is thus expressly resolved when protection is obtained under either of these statutes. However, for subject matter

26. 84 U.S. (17 Wall.) 453 (1873).

27. *Id.* at 456-57.

28. 35 U.S.C. §§ 161-164 (1988).

29. 7 U.S.C. §§ 2321-2583 (1988).

30. 35 U.S.C. § 163 (1988).

31. 7 U.S.C. § 2541 (1988).

protected by a utility patent, that question has not been addressed by either Congress or the courts.

If there is no statutory prohibition against self-propagation, and case law allows no restraint on the use of a patented product after sale by the patentee, is there any way the patentee of living subject matter can prevent purchasers from replicating it? Yes, because the "no restraint" rule is somewhat of an overstatement. In the context of "repair and reconstruction," the courts have recognized that there *are* some limits on the activities of the purchaser.

C. *The Doctrine of Repair and Reconstruction*

The Supreme Court has interpreted the doctrine of repair and reconstruction in a number of its decisions. In *Wilson v. Simpson*,³² the Court considered a planing machine intended for long-term use. The Court concluded that putting new blades into the planing machine when the blades had worn out from use was permissible repair of the invention necessary to preserve the purpose for which the machine was intended and sold.³³

More than thirty years later, in *Cotton-Tie Co. v. Simmons*³⁴ the Court considered the issue again in the context of a patent that claimed ties constructed from a metal buckle in combination with a metal band. The band was placed around a cotton bale and the ends were confined by the buckle. On each of the buckles the patent holder had stamped into the metal: "[l]icensed to use once only."³⁵ The accused infringer purchased the discarded straps and buckles as scrap iron, straightened the bands of the tie, punched holes in it, riveted the pieces together and formed new bands with the buckles attached. These ties were then sold to others who used them to bail cotton. In holding that this activity amounted to impermissible reconstruction of the invention, the Court focused on the fact that the ties, when removed from the bales of cotton, had served their complete intended function.³⁶

The Supreme Court later returned to the question of what constituted permissible repair and impermissible reconstruction in the case of *Aro Manufacturing Co. v. Convertible Top Replacement Co.*³⁷ The patent claimed in combination an automobile body of a flexible top fabric, supporting structures, and a mechanism for sealing the fabric against the side of the automobile body to prevent rain from entering. All the components of the combination were expected to last throughout the life of the car with the exception of the fabric component, which had a life span of approximately three years.³⁸ The Court reasoned that a purchaser is entitled to repair a worn out part within a patented combination to re-

32. 50 U.S. (9 How.) 109 (1850).

33. *Id.* at 125-26.

34. 106 U.S. 89 (1882).

35. *Id.* at 91.

36. *Id.* at 94-95.

37. 365 U.S. 336 (1961).

38. *Id.* at 337-38.

store the combination to its original function in order to realize the expected function and useful life of the patented combination.³⁹ When the activities effectively constitute making a new embodiment of the invention, that is "reconstruction" and is infringement.⁴⁰ In other words, sale by the patentee of the patented invention carries the implied condition that the purchaser be allowed to do those things necessary to enjoy the purchased material for its expected use, for its full anticipated life, but not to make additional or new copies or fit it for other uses, or give it new life.

D. *Application of the Reconstruction Doctrine to Self-Propagating Inventions*

As discussed above, what constitutes impermissible "reconstruction" depends, in large part, on the intended purpose of the product sold and the expected useful life of the product in that intended use. Applying the same principles to living matter provides an analysis that is flexible and rational.

The famous "oncomouse," for example, is entirely analogous to the single-use cotton bale tie. It is designed for one experiment, and one experiment exhausts its useful life. Replication is not intended and therefore would be an infringement.

Similarly, a patented crop seed is intended for propagation, but only one stage. Planting the seed and growing one plant from the purchased seed is expected and permitted, even though that action may result in the production of more seed. Planting the second generation, however, is not intended.

In the case of Chakrabarty's oil-eating microorganism, the patented life form must replicate extensively in order to perform its intended function. Accordingly, such replication would not constitute infringement.

For each of these three self-propagating inventions with three different intended uses, the repair/reconstruction rationale concludes that a sale authorizes, respectively, no reproduction, one stage of reproduction, and extensive reproduction. Applying those well-established principles produces reasonable, rational results.

E. *Licensing of Self-Propagating Inventions*

In addition to statutory restrictions, another way to control use of a product is to use contractual obligations. Where the patent holder makes and sells the patented invention, he is precluded from restricting the field in which the invention is used because the sale is deemed to exhaust the monopoly in that article.⁴¹

In contrast, where the patent holder grants a license to another to manufacture and sell the patented subject matter, he may restrict the

39. *Id.* at 343-46.

40. *Id.* at 346.

41. *United States v. Univis Lens Co.*, 316 U.S. 241, 250 (1942).

field in which that subject matter is used, even after the licensee has parted control.⁴² In fact, even purchasers with notice from a restricted licensee are bound by the limitations of the license.⁴³ Thus, if the patent holder can license his living matter, he can permit the useful, desired function but not the self-replicating one.

Another alternative for controlling the use of a product is to lease the essential material rather than sell it, a practice that is well-developed in the catalyst field. Leasing is particularly feasible when the living matter is a single relatively long-lived entity, such as a cow whose genetic makeup is modified to express a useful protein in its milk, or where the living matter, although it reproduces, remains reasonably constant in composition during its useful life, such as a microorganism culture that produces a desired product. It is more cumbersome when the user must realize profits by eventually selling the living item, for example, beef cattle.

Licensing is most feasible when the patent contains process claims, especially those processes that produce a product on which a royalty can be based. However, there are some limitations on the availability of process protection in the wake of decisions such as *In re Larsen*,⁴⁴ *In re Albertson*,⁴⁵ and *In re Durden*.⁴⁶

All of these cases involved a process that was generally known in the art, with the difference between the claimed process and the prior art process being that a starting material or resulting product was novel and unobvious, but with no unexpected result. In each case, the rationale was that although there was inventive subject matter in the starting material or the resulting product as a composition, such novelty did not confer on the inventor the right to claim old, manipulative steps that produced an expected result. This rationale was based on the realization that once a new chemical structure is defined, chemists of ordinary skill would readily recognize the applicability of conventional processes that would produce that structure or convert it into other structures. Because the invention of the new compound added nothing to those conventional processes, it would be unfair to allow the inventor to appropriate them. As summarized in *Durden*:

Of course, an otherwise old process becomes a *new* process when a previously unknown starting material, for example, is used in it which is then subjected to a conventional manipulation or reaction to produce a product which may also be *new*, albeit the *expected* result of what is done. But it does not necessarily mean that the whole process has become *unobvious* in the sense of § 103. In short, a *new* process may still be obvious, even when considered "as a whole," notwithstanding the spe-

42. *General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, 180-81 (1938).

43. *Id.* at 181-82.

44. 292 F.2d 531 (C.C.P.A. 1961), *cert. denied*, 370 U.S. 936 (1962).

45. 332 F.2d 379 (C.C.P.A. 1964).

46. 763 F.2d 1406 (Fed. Cir. 1985).

cific starting material or resulting product, or both, is not to be found in the prior art.⁴⁷

At the same time, the court cautioned against an overexpansive use of "black letter" rules that disregard the factual circumstances inherent in a section 103 analysis:

We are sure that there are those who would like to have us state some clear general rule by which all cases of this nature could be decided. Some judges might be tempted to try it. But the question of obviousness under § 103 arises in such an unpredictable variety of ways and in such different forms that it would be an indiscreet thing to do. Today's rule would likely be regretted in tomorrow's case. Our function is to apply, in each case, § 103 as written to the facts of disputed issues, not to generalize or make rules for other cases which are unforeseeable.⁴⁸

Despite the court's admonition, *Durden* has been widely relied upon as "black letter" law to reject process claims under section 103. In biotechnology cases, for example, these rejections have presented problems in patenting processes such as culturing cells containing DNA encoding a certain protein, and recovering that protein.

Because process claims are of special importance in biotechnology⁴⁹ some proponents have pressed for new legislation creating a per se class of patentable process inventions. In February, 1990, legislation was introduced to amend section 103 to provide that "a process of making a product shall not be considered obvious under this section if an essential material used in the process is novel under section 102 and otherwise non-obvious under section 103."⁵⁰

A more recent version of the bill, introduced in September, 1990, provided that:

[W]hen a process of making or using a machine, manufacture, or composition of matter is sought to be patented in the same application as such machine manufacture or composition of matter, such process shall not be considered as obvious under this section if such machine, manufacture, or composition of matter is novel under section 102 and nonobvious under this section. If the patentability of such process depends upon such machine, manufacture, or composition of matter, then a single patent shall issue on the application.⁵¹

While the proposed legislation appears on its face to be applicable

47. *Id.* at 1410 (emphasis in original).

48. *Id.* at 1411.

49. Of course, process claims generally have assumed greater importance because they give unique opportunities for protection against extraterritorial use. See 35 U.S.C. § 271(g); 19 U.S.C. § 1337 (1988). Use of a patented product abroad is not subject to the same prohibition. See *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 706 F. Supp. 94 (D. Mass. 1989).

50. H.R. 3957, 101st Cong., 1st Sess., 136 CONG. REC. H298 (1990).

51. H.R. 5664, 101st Cong., 2d Sess., 136 CONG. REC. H7825 (1990) (the "Boucher Bill").

to any field of technology, it was very clearly keyed specifically to a biotechnology dispute.

In 1983 Amgen, Inc. filed a patent application directed to DNA sequences encoding recombinantly produced erythropoietin, an essential blood protein that patients with diseased kidneys cannot produce in sufficient quantities. Amgen originally attempted to obtain claims to cover the manufacturing process for erythropoietin, but those claims were cancelled in view of a rejection based on the *Durden* decision.⁵² In October 1987, Amgen was granted a patent including claims to the gene encoding erythropoietin and recombinant host cells containing the gene.

Although the patent issued to Amgen claimed only the recombinant gene and the recombinant host cell, Amgen charged a foreign manufacturer with infringement under section 271(g) of the Patent Act for importation and sale of recombinant erythropoietin. Amgen argued that the court should construe the claims to the recombinant gene and host to include processes for making erythropoietin by expressing a gene so encoded.⁵³ Faced with the question of whether the Amgen patent included process claims, the court held that it did not based on the cancellation of such claims during prosecution.

Amgen also filed a complaint in the International Trade Commission (ITC) to block importation of the foreign-produced erythropoietin. The ITC dismissed the complaint by order, ruling that the imported erythropoietin was not within its jurisdiction under section 1337 of the Tariff Act of 1930⁵⁴ because the Amgen patent did not contain process claims.⁵⁵ On appeal, the Federal Circuit agreed that the ITC's exclusionary power did not reach such imports. However, the court vacated the Commission's order and remanded on the basis that the case should have been dismissed on the merits, not for lack of subject matter jurisdiction.⁵⁶

The Boucher Bill⁵⁷ was introduced as a direct consequence of the *Amgen, Inc. v. United States International Trade Commission* situation.⁵⁸ One purpose of the bill is to overrule legislatively the holding in *Durden*; another is to amend section 1337 of the Tariff Act,⁵⁹ to grant to the ITC the jurisdiction it found lacking in the *Amgen* erythropoietin case.

The need for this bill has been debated extensively. Supporters of the bill contend that *Durden* acts as an obstacle to the development of the

52. Amgen has subsequently succeeded in overcoming the rejection of its process claims, but those claims have failed to issue pending the outcome of an interference proceeding.

53. 706 F. Supp. at 97.

54. 19 U.S.C. § 1337 (1988).

55. *In re Certain Recombinant Erythropoietin*, 10 U.S.P.Q.2d (BNA) 1906, 1911 (U.S.I.T.C. 1989), *vacated*, *Amgen, Inc. v. United States Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990).

56. 902 F.2d at 1540.

57. See *supra* notes 50-51 and accompanying text.

58. 902 F.2d 1532 (Fed. Cir. 1990). The bill was deliberately drafted in general terms to avoid the sensitivity to industry specificity.

59. 19 U.S.C. § 1337(a)(1)(B) (1988).

United States biotechnology industry, because the essence of biotechnology is in the application of known processes to novel starting materials. Methods for expression of a novel gene to produce the corresponding protein usually use well-established vectors and techniques. The "inventiveness" most often lies in the application of those techniques and materials to express the novel gene. Viewed from the point of view of transgenic technology, the physical manipulations required to produce and reproduce an animal with foreign DNA introduced are essentially established. Supporters also argue that automatic patentability for a class of process patent claims, directed to processes of making patentable products, will reduce the workload of the PTO, which has been partly responsible for the long pendency of biotechnology applications.

Opponents of the bill raise concerns that per se patentability (1) is alien to our concepts of invention, (2) would encourage an applicant to "overclaim" in the application, that is, include process claims encompassing a large number of manipulative steps not covered by the inventive concept, and (3) is unnecessary to solve any perceived problem.

Creating black letter laws of what is patentable is as wrong as creating ones for what is not patentable. Under the proposed bill, the inventor of a new ratchet wrench could claim the process for bolting together metal parts, using the wrench, then the process for assembling cars by bolting together metal parts using the new wrench, and so on. Invoking the provisions of section 271(g) of the Patent Act or the jurisdiction of the ITC under section 1337 of the Tariff Act, the wrench inventor can then enjoin importation or sale of cars. Per se patentability creates new problems at least as absurd as the ones it is intended to solve.

Again, the answer lies in living within our existing legal framework. *Durden* and its predecessors do not stand alone as guidelines to the patentability of processes involving the use of previously unknown materials. In *In re Mancy*,⁶⁰ for example, the claims related to a process of preparing the known antibiotic, daunorubicin, by aerobically cultivating a previously unknown microorganism. One of the appealed claims recited a:

process for the production of Daunorubicin which comprises aerobically cultivating *Streptomyces bifurcus*, strain DS 23,219 (NRRL 3539), of [sic, or] a daunorubicin-producing mutant thereof, using an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances, and separating daunorubicin formed during the culture.⁶¹

The PTO examiner rejected the claims on the basis that it was not patentable to produce a known antibiotic from either a different strain of the same species of organism or a different species of the same genus without something more than merely the use of another source from the

60. 499 F.2d 1289 (C.C.P.A. 1974).

61. *Id.* at 1290.

same field of sources of these products.⁶² The Board of Appeals agreed that the choice of a different strain of the same microorganism was *prima facie* obvious.⁶³

On appeal, the Court of Customs and Patent Appeals reversed the Board, holding that "[w]ithout *Streptomyces bifurcus*, strain DS 23,219, knowledge of which is supplied by appellants' application and availability of which is supplied by appellants' deposit of the microorganism with the Department of Agriculture, one skilled in the art would not find it obvious to produce daunorubicin by aerobically cultivating *Streptomyces bifurcus*."⁶⁴ Appellants did not have any allowed claims to the novel strain of *Streptomyces* because, although not shown in the art of record, the strain was considered unpatentable as a "product of nature."⁶⁵ However, the court emphasized that a patentable starting material was not required for the unobviousness of the method of use claims.⁶⁶

That reasoning was carried further by the Federal Circuit in the recent case, *In re Pleuddemann*.⁶⁷ The invention related to a silane coupling agent that included the reaction product of an isocyanatoalkyl ester with an aminoorganosilane, and imparted superior moisture resistance to mineral-filled unsaturated polyesters, as well as other unsaturated resin composites.⁶⁸ The silane compounds improved the mechanical properties of the final product by coupling or bonding the polyester resins to the fiberglass filling material.⁶⁹ Noting that silanes had been used previously as coupling agents, the examiner rejected claims directed to a process for bonding a polymerizable material to a mineral filler, and a method for priming a surface to improve its bonding to particular organic resins on the authority of *Durden*, and the Board of Appeals affirmed.

The Federal Circuit, however, recognized that there are process inventions in which the new composition and the manner of using it are highly interrelated, so that the composition gives special or new value to the process steps. In such cases, "the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. 112, *all aspects of what they regard as their inventions, regardless of the number of statutory classes involved.*"⁷⁰ On the specific facts of the case before it, the court held that:

It is the properties of appellant's compounds as bonding/priming agents for certain polymers and fillers or support surfaces that give them their utility. . . . [T]he compounds and their use are but different aspects of, or ways of looking at, the same in-

62. *Id.* at 1291.

63. *Id.*

64. *Id.* at 1292.

65. *Id.* at 1294.

66. *Id.* See *In re Schneider*, 481 F.2d 1350 (C.C.P.A. 1973).

67. 910 F.2d 823 (Fed. Cir. 1990).

68. *Id.* at 824.

69. *Id.*

70. *Id.* at 826 (emphasis in original).

vention and consequently that invention is capable of being claimed both as new compounds or as a new method or process of bonding/priming. On the other hand, a process or method of making the compounds is a quite different thing; they may have been made by a process which was new or old, obvious or nonobvious. In this respect, therefore, there is a real difference between a process of making and a process of using and the cases dealing with one involve different problems from the cases dealing with the other.⁷¹

By looking at the *interrelationship* between the process and the novel, unobvious composition, *Pleuddemann* provides a rational, flexible mechanism that the proposed statutory revision does not. The invention of a new ester adds nothing to the old, known manipulative steps of coupling an acid and an alcohol, and does not justify a claim to a process invention. The invention of a new ratchet mechanism for a wrench adds nothing to the process of bolting together metal panels. It may be fairly argued, however, that the invention of a new DNA sequence *does* directly impact the expression of that sequence into a useful protein.

Pleuddemann provides the rationale for distinguishing appropriate situations of patentability and awarding patent rights where deserved. The result was achieved by considering, not the special needs of biotechnology, but rather the general premises of patent law on which the patent system is based.

F. *Infringement of Biotechnology Inventions*

Assessing infringement of a biotechnology patent raises a number of novel questions. Do the established doctrines of claim construction and equivalence work for patents that involve living matter? When is one microorganism equivalent to another? How does one decide whether changes in base sequence or amino acid sequence are sufficient to avoid a claim to a defined sequence of DNA or to a protein? Is a patent based on a protein obtained only in minuscule quantities by isolation from natural sources infringed by a product produced in commercial quantities through a later-developed, inventive recombinant process?

In order to determine the scope of a patent holder's rights in the patented invention, "resort must be had in the first instance to the words of the claim."⁷² Whether an accused device, method or composition infringes the patent necessarily begins with this step, "and then the trier must decide whether the claims cover the accused device."⁷³

"If properly construed claims read on the infringing product, there is literal infringement."⁷⁴ Even if a product does not literally infringe the claims, it can still be held to infringe under the doctrine of

71. *Id.*

72. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950).

73. *Palumbo v. Don-Joy Co.*, 762 F.2d 969, 974 (Fed. Cir. 1985).

74. *Atlas Powder Co. v. E.I. Du Pont de Nemours & Co.*, 750 F.2d 1569, 1579 (Fed. Cir. 1984).

equivalents.⁷⁵ This judicially created doctrine was designed to protect a patent holder from an infringer who appropriates the invention but avoids the literal terms of the claims. As recognized by the Supreme Court in *Graver Tank*,

to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.⁷⁶

Therefore, “[t]o temper unsparing logic and prevent an infringer from stealing the benefit of an invention,”⁷⁷ a patent holder can invoke the doctrine against an accused device “if it performs substantially the same function in substantially the same way to obtain the same result.”⁷⁸

Equivalence requires that each element recited in the claim find a counterpart in means, function and result in the accused device.⁷⁹ A patentee cannot, by equivalence, claim what is in the prior art. To determine whether a particular range of equivalents is barred by the prior art, the conceptual exercise is to rewrite the claim to include the accused device literally, then test it for patentability.⁸⁰ There have been only a handful of decisions applying these principles to biotechnology inventions.

In *Scripps Clinic & Research Foundation v. Genentech, Inc.*,⁸¹ Scripps charged Genentech with infringement of claims directed to Factor VIII:C, one of the factors used to activate the proteins that permit blood clotting. Scripps obtained a patent for the products of and a process for purifying and concentrating Factor VIII:C from human and porcine blood plasma.⁸² The Scripps patent included both process and product-by-process claims. A reissue of this patent subsequently added claims directed to human Factor VIII:C preparations having specific purity and concentration characteristics.⁸³

Genentech was accused of infringement based on its manufacture of Factor VIII:C by recombinant techniques. Genentech scientists se-

75. *Id.*

76. 339 U.S. at 607.

77. *Id.* at 608 (quoting *Royal Typewriter Co. v. Remington Rand*, 168 F.2d 691, 692 (2d Cir. 1948)).

78. *Id.* (quoting *Sanitary Refrigeration Co. v. Winters*, 280 U.S. 30, 42 (1929)).

79. *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1259-60 (Fed. Cir. 1989); *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 935-36 (Fed. Cir. 1987), *cert. denied*, 485 U.S. 961 (1988).

80. *Wilson Sporting Goods Co. v. David Geoffrey & Assoc.*, 904 F.2d 677, 684 (Fed. Cir. 1990).

81. 666 F. Supp. 1379 (N.D. Cal. 1987), *modified*, 678 F. Supp. 1429 (N.D. Cal. 1988), *aff'd in part, rev'd in part, vacated in part, and remanded*, Nos. 89-1541, -1542, -1543, -1646, -1647 (Fed. Cir. March 11, 1991) (consolidated appeal in which the Federal Circuit reversed and remanded on the infringement issues).

82. U.S. Patent No. 4,361,509.

83. 666 F. Supp. at 1383.

quenced the protein, cloned the Factor VIII:C gene, then cloned the cDNA encoding the actual coding sequence, expressed the DNA in a mammalian cell system, and devised a protein purification process. This process avoided the use of human plasma pools, which potentially contained infectious agents including HIV-1, the etiological agent of AIDS, and monoclonal antibodies, and made large-scale production feasible.

Among the claims asserted to be infringed by Genentech were the following product claims:

24. A human VIII:C preparation having a potency in the range of 134 to 1172 units per ml. and being substantially free of VIII:RP.

25. A human VIII:C preparation of claim 24, wherein the VIII:C concentration is at least 160,000 fold purified relative to VIII:C in plasma.⁸⁴

Also asserted were product-by-process claims, including:

13. Highly purified and concentrated human or porcine VIII:C prepared in accordance with the method of claim 1.

Claim 1 as incorporated by reference in Claim 13 recited:

1. An improved method of preparing Factor VIII procoagulant activity protein comprising the steps of

(a) adsorbing a VIII:C/VIII:RP complex from a plasma or commercial concentrate source onto particles bound to a monoclonal antibody specific to VIII:RP,

(b) eluting the VIII:C,

(c) adsorbing the VIII:C obtained in step (b) in another adsorption to concentrate and further purify same,

(d) eluting the adsorbed VIII:C, and

(e) recovering highly purified and concentrated VIII:C.⁸⁵

Genentech argued that it did not infringe the Scripps product claims because its Factor VIII:C was not derived from human blood plasma. On a motion for summary judgment on the issue of Genentech's infringement of the product claims, the district court considered whether "the asserted product claims must be interpreted to apply solely to concentrates of Factor VIII:C derived directly from human blood plasma or whether they extend also to other concentrates of Factor VIII:C having the same characteristics as those derived from human blood plasma."⁸⁶

The court held that the claims were directed to preparations of the disclosed purity or concentration having characteristics specific to Factor VIII:C found in humans, and that Scripps was entitled to a claim for purified Factor VIII:C, whether derived through the disclosed process of the specification, or any other process achieving the same result.⁸⁷ The court granted summary judgment, concluding literal infringement as to product-by-process claim 13 on the basis that the same process was used

84. *Id.* at 1385.

85. *Id.*

86. *Id.* at 1389.

87. *Id.* at 1390.

to produce the claimed product.⁸⁸ With respect to the product claims, the court held that "Human Factor VIII:C as claimed in the patent therefore applies to any Factor VIII:C preparation, regardless of how produced, having the same material structural and functional characteristics as the plasma-derived preparation."⁸⁹

On the question of whether Factor VIII:C produced by recombinant processes infringed the product claims so interpreted, the court explained:

The production of Genentech's recombinant Factor VIII:C, although it takes place in hamster rather than human cells, is directed by the controlling human gene. . . . That gene, transplanted from a human cell to a hamster cell, determines the amino acid sequence and other fundamental structural traits and functions of the protein.⁹⁰

The court concluded that "[i]n effect, Genentech's process transfers the site of Factor VIII:C production (1) from the human body to the laboratory and (2) from the cells of the human kidneys, liver, spleen and lymph glands to the cells of the hamster kidneys. The master plan for Factor VIII:C production, however, remains constant."⁹¹

In response to Genentech's argument that there may be substantial changes in the protein product following its translation from the gene, the court found that any such differences resulting from post-translational changes in the protein were not relevant, as there was no evidence that they alter the *in vitro* biological activity of the enzyme.⁹² Accordingly, the court held that Scripps was entitled to an infringement judgment on all but two product claims (on which insufficient evidence of infringement had been provided) because the recombinant Factor VIII:C was structurally and functionally the same as plasma-derived Factor VIII:C.⁹³

The issue of whether infringement of product or composition claims can be avoided by varying the structure of claimed peptides was considered in *Hormone Research Foundation, Inc. v. Genentech, Inc.*⁹⁴ Hormone Research Foundation sued Genentech on the basis that Genentech's recombinant human growth hormone product infringed

88. *Id.* at 1388. The district court subsequently modified its order by deleting reference to claim 13, on the basis that the activity alleged to infringe the claim occurred before its reissue date. 678 F. Supp. at 1433.

89. *Id.* at 1390.

90. *Id.* at 1391.

91. *Id.* at 1392.

92. *Id.* at 1394.

93. The patent in *Scripps* was subsequently invalidated in *Scripps Clinic & Research Found. v. Genentech, Inc.*, 707 F. Supp. 1547 (N.D. Cal. 1989), for failure of disclosure of best mode, for inequitable conduct, and for failure of the reissue patent to comply with reissue requirements. In a very recently decided consolidated appeal, the Federal Circuit *inter alia* reversed and remanded on these issues. *Scripps Clinic & Research Found. v. Genentech, Inc.*, Nos. 89-1541, -1542, -1543, -1646, -1647 (Fed. Cir. March 11, 1991) (consolidated appeal).

94. 708 F. Supp. 1096 (N.D. Cal. 1988), *aff'd in part, vacated in part, and remanded*, 904 F.2d 1558 (Fed. Cir. 1990).

several claims of their patent,⁹⁵ including Claim 12, which concerned "a composition of matter consisting essentially of a synthetic, biologically active substance which has a structure corresponding to FIG. 2 of the accompanying drawing."⁹⁶

The accused recombinant product differed from the sequence structure of FIG. 2 in that it had two additional amino acids, and several slightly different amino acids in certain positions of the sequence structure. On a motion for partial summary judgment, the district court held that the claims were not literally infringed because the "[t]he properties are different and in chemical structures as sensitive as these the literal infringement showing must be exacting."⁹⁷ The district court interpreted the claim term "corresponding" to limit the claimed protein sequence to the identical amino acid sequence and conformation depicted.⁹⁸

Further, the court held that infringement was precluded under the doctrine of equivalents because of prosecution history estoppel.⁹⁹ It interpreted certain arguments in the prosecution of the subject patent to limit the claims to the sequence structure shown in FIG. 2, as opposed to broadly including human growth hormone and its derivatives.¹⁰⁰

Although it did not agree with the district court's interpretation of the term "corresponding" in construing the claims, the Federal Circuit nonetheless affirmed the finding of no literal infringement on the basis that identity in all respects to the sequence of FIG. 2 was consistent with both the specification and the prosecution history.¹⁰¹ However, the Federal Circuit vacated the portion of the judgment holding that the claims were not infringed under the doctrine of equivalents on the basis that the meaning of the statements made during prosecution was ambiguous, leaving certain factual issues unresolved.¹⁰² Accordingly, the case was remanded to the district court to determine the intent and effect of arguments made during prosecution.

*Genentech, Inc. v. Wellcome Foundation, Ltd.*¹⁰³ involved the issue of post-invention improvements and what limits should apply to the use of the doctrine of equivalents. The patents in suit included claims directed to human glycoprotein tissue plasminogen activator (t-PA). As it exists in the human body, t-PA is composed of 527 amino acids, and is divided into five "domains."¹⁰⁴ One of the patents claimed human t-PA isolated

95. U.S. Patent No. 3,853,833.

96. 708 F. Supp. at 1099.

97. *Id.* at 1102.

98. *Id.* at 1101.

99. Prosecution history estoppel, also known as file wrapper estoppel, prevents a patentee from recapturing, during an infringement action, claim scope surrendered during prosecution of the patent application.

100. 708 F. Supp. at 1106.

101. *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1563-64 (Fed. Cir. 1990).

102. *Id.* at 1567.

103. 14 U.S.P.Q.2d (BNA) 1363 (D. Del. 1990).

104. *Id.* at 1365.

from melanoma cells as follows:

Human plasminogen activator, having thrombolytic properties, immunologically distinct from urokinase and having a specific activity of about 500,000 IU/mg. using the WHO First International Reference Preparation of t-PA (tissue plasminogen activator) as assay standard or a specific activity of about 90,000 IU/mg. using the WHO First International Reference Preparation of urokinase as assay standard.¹⁰⁵

Another of the patents asserted to be infringed included claims directed to genetically engineered cells capable of producing t-PA:

1. A DNA isolate consisting essentially of DNA sequence encoding human tissue plasminogen activator;
2. A recombinant expression vector containing a DNA sequence encoding human tissue plasminogen activator, wherein the vector is capable of expressing human tissue plasminogen activator in a transformed microorganism or cell culture; and
3. A cell culture capable of expressing human tissue plasminogen activator, obtained by transforming a mammalian cell line with a vector according to claim 3 [sic, 2].¹⁰⁶

The accused products included met-t-PA, which differed from t-PA only in a substitution of the amino acid methionine for valine at position 245, and a variant of met-t-PA, known as FE1X, in which the amino acids in two of the "domains" had been deleted.¹⁰⁷

The district court considered summary judgment motions made by both parties based on the asserted infringement of the two patents. Having interpreted the claims to require a human t-PA immunologically distinct from urokinase, and with a specific activity of about 500,000 IU/mg., the district court did not find literal infringement because the products had a methionine substitution distinguishing them from the human t-PA claimed, and because the specific activity of met-t-PA was different from that claimed.¹⁰⁸

Regarding the question of infringement under the doctrine of equivalents, the district court noted that the patented product stimulated dissolution of a fibrin clot by enzymatic cleavage of plasmin, and, applying the *Graver Tank* function-way-result test,¹⁰⁹ held:

There is no question that the function and result of both FE1X and met-t-PA is likewise to stimulate dissolution of fibrin clots through the cleavage of plasminogen to plasmin. In this case, any distinction between the patented product and the accused products hinges on the means of producing the cleavage of plasminogen to plasmin.¹¹⁰

Summary judgment was precluded on this issue, however, because

105. *Id.* at 1367.

106. *Id.*

107. *Id.* at 1368.

108. *Id.* at 1370.

109. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

110. 14 U.S.P.Q.2d at 1370.

of material issues of fact with regard to the "means" used by the accused products in performing their function. Accordingly, the court held:

The trier of fact will have to determine the impact of both the deletion of the F and E regions and the substitution of methionine on the cleavage of plasminogen. So, although the court is persuaded that Genentech's t-PA and Genetic Institute's FEIX have the same intended result, it is unclear at this point if they achieve it by the same means.¹¹¹

While strictly in accordance with classic analyses of equivalence, the court's rationale in this case portends some substantial problems. Application of the doctrine of equivalents is straight-forward when the relationship between structure and function is well defined, for example as in most mechanical devices, or when a chemical equivalence can be understood through well-accepted principles of reaction mechanisms or physical properties.

When structure-function relationships are less well understood, or when it is not possible to demonstrate to the trier of fact exactly how the invention functions, as in biotechnology inventions that involve complex systems of proteins, genes, or cells, for practical purposes the test of equivalency may reduce to an examination of the observable results produced by the accused embodiment and the patented invention.

In the t-PA case, for example, the evidence involved the mode of binding of t-PA and its analogs to the fibrin substrate, and the half-life in circulation following injection into animals. The court found that where "there are genuine issues of material fact with regard to the question of means, that cannot be resolved,"¹¹² summary judgment is precluded; such issues must be resolved by a lay jury. The jury's eventual finding of the accused embodiment as equivalent to the patented invention contributed to Wellcome's decision to discontinue its six-year effort to develop t-PA in the United States.¹¹³

With decisions on patent infringement having such large potential impact on companies and the public, it is important that they be fairly and rationally reached. Identity of function, means and result must indicate, in biotechnology inventions, more than just that the same general overall effect, as for example clot dissolving, is reached by both. Of course, inconsequential alterations in an amino acid sequence made to avoid literal correspondence should not escape infringement for the simple reason that a fundamental purpose of the doctrine of equivalents is to avoid fraud on the patent; a second-comer should not be allowed to appropriate the patentee's contribution to the art. At the same time, there must be room for independent innovation and development. Improvements in effectiveness may make the difference between something that is useful in the real world and something that is not.

Equivalence analyses should always consider the benefit the accused

111. *Id.* at 1371.

112. *Id.*

113. Wall St. J., May 11, 1990, at B1, col. 6.

infringer derived from the patentee's work. The balance between unfair appropriation of the claimed subject matter and the legitimate activities of "designing around" the patent has always been a factor in equivalence cases. The ultimate consideration in such a balance is whether it was the patentee or the accused infringer who more substantially enriched the art, and whether the accused infringer's activity was mechanical, predictable substitution or original innovation.

Tremendous advances have been made since the concept of an antibody was first developed by Landsteiner,¹¹⁴ in terms of a haptene-specific protein, to the current view of an antibody having three-dimensional structure, with well defined sets of gene segments separately encoding variable, joining, and constant regions. Viewed on a macro level, a hypothetical "antibody" invention in 1910 would likely be considered equivalent under a function-way-result analysis to an "antibody" in 1990. If a more refined analysis were conducted, however, the two "antibody" devices would be distinguished by their different structural and functional elements. A better understanding of how living systems "work" would help in a determination of whether two things work in the same way.

Finally, we, as advocates, must learn how best to communicate sophisticated and complex scientific principles to a lay trier of fact. That, however, is not unique to biotechnology. In almost every field, from computer science to pharmaceutical research, the level of ordinary skill in the art is that of a highly trained and educated specialist who uses words and concepts wholly outside the experience of any judge or jury. Effective communication of this information in understandable terms presents the greatest challenge to the creativity and preparedness of advocates, without regard to the technical field of specialty.

G. *The "Farmer's Exemption" and Transgenic Animals*

Among the concerns that have been expressed regarding the patenting of farm animals are arguments by certain farm coalitions that patenting will harm small and family farms by raising prices to farmers of new breeds of animals. Some opponents of animal patenting also fear that patenting of animals will lead to an overconcentration in the animal sector in industry. Opponents are also concerned that patenting of animals will result in impoverishing the gene pool.

Although depletion of the gene pool is a valid concern in breeding endeavors, this consideration must be weighed against the reality of transgenic technology. First, there is really nothing new about attempts to create new life. Selective breeding to produce animals with particular attributes — bigger, leaner, faster growing, stronger, healthier — has long been employed. Genetic engineering techniques are simply a better, more efficient means to accomplish that purpose. Furthermore, genetic alterations in transgenic animals are limited to confined changes,

114. K. LANDSTEINER, *THE SPECIFICITY OF SEROLOGICAL REACTIONS* (1936).

for example the introduction of a gene encoding growth hormone, or a gene rendering the animal exquisitely susceptible to cancer. The goal of transgenic animal creation is to produce a variety of animals having a variety of desired properties, much like the oil-eating bacteria of Chakrabarty. The purpose of transgenic research is not to produce a single new breed to the exclusion of other breeds, anymore than Chakrabarty intended to replace all *Pseudomonas* with the novel oil-eating variety.

With respect to whether patenting animals will lead to industrial domination of the animal breeding sector, the purpose of the patent system must be considered. The grant of patents is justified for *all* areas of technology because it rewards innovation, encourages disclosure and stimulates competitiveness by permitting innovators to "design around" the patented subject matter. The protection of a patent is available to industrial giants, fledgling companies, and individual inventors alike. Indeed, patenting is the way start-up companies gain a foothold in the market. Concerns about the economic effects of transgenic animal patenting on farmers has prompted legislation specifically drafted to protect rights in transgenic inventions. In 1988, the Transgenic Animal Patent Reform Act¹¹⁵ was introduced in the House of Representatives in which an infringement exemption was proposed for farmers and researchers and was subsequently approved by the Judiciary Committee. The bill was reintroduced the following year in March 1989,¹¹⁶ proposing the following additional new subsections to section 271 of the Patent Act, the statute governing infringement:

(h)(1) It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation or sell such animal or the offspring of such animal.

(2) Notwithstanding the provisions of paragraph (1), it shall be an act of infringement for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal.

(3) For purposes of paragraphs (1) and (2)

(A) the term "transgenic farm animal" means a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal; and

(B) the term "farm animal" means any animal used or intended for use as food or fiber.

This exemption was patterned after the crop exemption provided in the Plant Variety Protection Act (PVPA), which recites in pertinent part:

[I]t shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seed-

115. H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H4992 (1988).

116. H.R. 1556, 101st Cong., 1st Sess., 135 CONG. REC. H835 (1989).

ing purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section: *Provided*, That without regard to the provisions of section 2541(3) of this title it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes, provided such sale is in compliance with such State laws governing the sale of seed as may be applicable.¹¹⁷

The perceived economic threat to farmers was the primary reason for the proposed "Farmer's Exemption." Upon closer analysis, however, the economic detriment argument does not match economic reality. The farmers will be under no obligation to purchase transgenic animals. The choice of whether or not to purchase a transgenic breed will simply be a business decision, much as the decision is made to purchase an improved piece of farm equipment. The farmer will weigh the cost of the animal against the expected benefits and on that basis determine whether purchase of the animal is economically sound.

Indeed, transgenic animals may prompt an entirely new line of business for some small farmers. For example, transgenic animals that produce desirable proteins such as insulin, interferons, and blood factors are presently being developed. These animals may provide the means for protein production as a new line of farming.

The Farmer's Exemption, as proposed for transgenic animals, has met considerable, and justified, opposition from the biotechnology industry. It is viewed as a compulsory license that would unfairly eliminate a significant source of revenue to the patent holder. In evaluating the fairness of this exemption, it is useful to look at the type of protection to which this form of exemption has previously been applied.

When Congress passed the Plant Patent Act, protection was only made available to asexually reproduced plants, due to concerns that plants would not otherwise breed true to seed. Subsequent technological advances permitted reliable reproduction and the PVPA was enacted in 1970 to provide protection for sexually reproduced plants. A PVPA certificate is not a patent, however, and offers only a limited scope of protection.

The requirements to obtain a PVPA certificate are less rigorous than the standards for a utility patent. The plant must be a novel variety, but this requirement is met if there is "distinctness," "uniformity," and "stability."¹¹⁸ There is no non-obviousness provision in the PVPA and, unlike the requirements for a utility patent,¹¹⁹ there is no enabling provision that must be met before a certificate can issue. The Act requires only that the description of the plant be as adequate and complete as possible.¹²⁰ A seed deposit must also be submitted with the

117. 7 U.S.C. § 2543 (1970) (emphasis in original).

118. 7 U.S.C. § 2401(a) (1988) (defines terms).

119. 35 U.S.C. § 112 (1988).

120. 7 U.S.C. § 2422(2) (1988).

application to the Plant Variety Protection Office.¹²¹

PVPA certificates protect a single plant variety. Multiple claims and broad coverage, possible with utility patents, cannot be obtained through the PVPA certificate application process.

With respect to enforcement, the PVPA specifically enumerates eight acts that constitute the totality of infringement. Accordingly, there is no provision for the doctrine of equivalents under the PVPA.

Thus the rights and requirements attendant a PVPA certificate are plainly different from the rights accorded under the patent system and the exemptions are not rationally transferred.

The crop exemption of the PVPA was founded on a historical right of tenant farmers to reserve seed for the next year's crop. Whatever the basis for its inclusion in the PVPA, engrafting its analogue onto utility patent protection flies in the face of a long history of abhorrence of compulsory licensing. If the PVPA becomes the stepping stone for the first form of statutory compulsory licensing, the farmers' animal exemption is likely to be the stepping stone for the next incursion into the patent holder's traditional rights. It is neither logically justified nor good sense in a world in which we are trying to convince other countries that strong enforcement of patents is essential, and compulsory licenses are counter-productive.

IV. CONCLUSION

The question first posed was whether we need to change the legal principles relating to intellectual property, including patentability and infringement, to accommodate biotechnology inventions. Quite plainly the answer is no. As with any emerging technology it will take some time for fine tuning on a case-by-case basis, but on the whole these principles do appear to be working and should not be changed.

121. *Id.* § 2422(3).

ADDENDUM

One of the principal concerns faced by authors is the very real risk that new and important decisions will issue during the time required for editing, organizing and printing of the article. That happened to us; two landmark decisions of the Court of Appeals for the Federal Circuit were handed down within the two weeks after our text was sent to the printer. Although it was then too late to revise the manuscript and still make the publisher's deadline, the Law Review graciously accommodated us by allowing us to include this addendum to discuss some of the ramifications of *Amgen, Inc. v. Chugai Pharmaceutical Co.*¹ and *Scripps Clinic & Research Foundation v. Genentech, Inc.*² Each of these decisions merits a full article devoted to it. We will discuss, in brief summary, only the points most germane to biotechnology.

The two decisions are of immediate and considerable interest because they add to a relatively small body of appellate precedent in biotechnology, and they illustrate how the court can use existing principles to resolve disputes in this new field.

THE BASIC FACTS OF *AMGEN*

In *Amgen*, the Federal Circuit reviewed determinations of validity and infringement involving U.S. Patent 4,703,008 ('008 patent) issued to Dr. Fu-Kuen Lin, an employee of Amgen, and U.S. Patent No. 4,677,195 ('195 patent) issued to Dr. Rodney Hewick and assigned to Genetics Institute (GI). Amgen's '008 patent claimed purified and isolated DNA sequences encoding erythropoietin (EPO), including any sequence that encoded a protein that exhibited EPO-like activity, and host cells containing the cloned sequences. GI's '195 patent claimed homogeneous EPO compositions of defined minimum purity (stated in terms of specific activity), and was based on the purification of the protein from natural sources. Amgen sought to enforce the '008 patent against GI. GI, in turn, asserted that Amgen's recombinant EPO infringed GI's patent.

GI contended the '008 patent was invalid because (i) the isolated, purified DNA sequence for EPO was previously invented by GI's Dr. Edward Fritsch, (ii) the Amgen disclosure was not commensurate with the scope of its claims, and (iii) Amgen did not disclose the "best mode" (the best transfected cell) of carrying out the invention. Amgen attacked the validity of the GI patent on the theory that the minimum specific activity recited in the claims could not be achieved by the disclosed purification process.³

1. Nos. 90-1273, 90-1275 (Fed. Cir. Mar. 5, 1991).

2. Nos. 89-1541, 89-1542, 89-1543, 89-1646, 89-1647 (Fed Cir. Mar. 11, 1991).

3. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 13 U.S.P.Q.2d (BNA) 1737, 1738-40 (D. Mass. 1989).

HOW IS AN INVENTION MADE AND HOW FULLY DOES IT
HAVE TO BE DESCRIBED

Typically, a research project is prompted by the realization that there is a protein that performs some useful function. Knowing that, the researcher deduces that there is a gene that expresses that protein which, if isolated and put into a suitable environment, will enable the production of the protein in large quantities. Often, purification of the protein from a natural source is a key step in the understanding of both its existence and function. When obtained in sufficient purity, the natural protein can be analyzed to determine the sequence of amino acids composing its structure. The purified natural protein itself typically has utility and is usable in therapy. However, if the gene can be obtained and expressed, the quantity and purity of the product and the efficiency of its production can usually be enhanced.

The search for the human gene is typically carried out by using a suitable complementary construct to probe a DNA library. The probe may be a DNA fragment obtained from another animal species. The probe may also be constructed synthetically from knowledge of the amino acid sequence of the naturally derived protein, although this approach is complicated because a given amino acid may correspond to two or more different DNA codons. Thus, synthetically constructing all of the possible variations that encode for a specified amino acid sequence can be a formidable job.

When the gene is obtained and sequenced, the researcher may explore ways to improve it by adapting it for expression in a variety of cells or by modifying the codon sequence to produce a protein with one or more variations in its amino acid structure in the hope of producing enhanced potency, resistance to degradation or some other desirable quality.

If the realization of the existence of the protein from a natural source is sufficient to predict the existence of the gene producing it, and using probes to obtain the gene is within the ordinary skill of the art, at what point is the invention of the isolated gene made? In other words, is the level of skill in biotechnology so high that isolation and expression of the gene are now a routine matter whose success is assured once some basic information is in hand?

In *Amgen*, inventor Lin probed a genomic DNA library using two sets of probes, each of which encoded the same amino acid sequence, but incorporated different combinations of DNA codons. GI contended that the isolated EPO gene was previously invented by Dr. Fritsch, who had earlier developed the same probing strategy to obtain it, even though he did not successfully perform the physical operations until after Lin did.⁴

4. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, Nos. 90-1273, -1275, slip op. at 8-9 (Fed. Cir. Mar. 5, 1991) (LEXIS, Genfed library, U.S. App. file 3481; WESTLAW, CTAF database 27262), *aff'g in part, rev'g in part, vacating in part* 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989).

The court found that, while Fritsch had the goal of obtaining the isolated EPO gene, whatever its identity, and even had an idea of a possible method of obtaining it, he did not invent the claimed purified and isolated DNA sequence or possess a viable method for obtaining it until he actually carried out the steps and realized the goal, which he did later than Lin. Until then, the court said, what Fritsch had was "simply a wish to know the identity of any material with [EPO] biological activity."⁵ In reaching that result, the Federal Circuit simply considered that "[a] gene is a chemical compound, albeit a complex one"⁶ and it therefore applied the "well established" law of conception as it had been developed in other chemical cases that "[c]onception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it."⁷ Thus, in biotechnology inventions, as in other chemical inventions, "when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated."⁸

Another issue in biotechnology inventions is whether having the natural gene permits the inventor to claim all possible variations of its structure. That was also treated in *Amgen*.

The '008 patent included generic claims directed to all possible DNA sequences encoding analogs of EPO having EPO-like activity. For example, claim 7 reads:

A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglobin synthesis or iron uptake.⁹

The trial court found that prophetic claim to be broader than what was "enabled" by the disclosure of the specification.¹⁰

Under section 112 of the Patent Act,¹¹ the specification must contain sufficient disclosure to enable one of skill in the art to make and use the invention as claimed without undue experimentation. Substitution at a single amino acid site could result in over 3,600 different EPO analogs, and over a million analogs could be produced by substitution at three different amino acid sites.¹² The number of claimed DNA se-

5. *Id.* at 11.

6. *Id.* at 10.

7. *Id.* at 10-11.

8. *Id.* at 11.

9. *Amgen*, 13 U.S.P.Q.2d at 1741.

10. *Id.* at 1776.

11. 35 U.S.C. § 112 (1988).

12. *Amgen*, slip op. at 27.

quences that could produce a product with EPO-like activity was therefore potentially enormous.

In reaching its conclusion of insufficiency of disclosure, the district court relied on the inability to predict with certainty which of those many analogs would have the desired activity, noting that Amgen was unable to do that even after five years of experimentation.¹³ The Federal Circuit agreed the disclosure was inadequate but rested its decision on established principles of what is required for an enabling chemical disclosure rather than any unusual degree of unpredictability in biotechnology cases. Citing *In re Angstadt*,¹⁴ the Federal Circuit held that section 112 does not mandate that a patent applicant test all of the embodiments of the invention, but does require a disclosure of how to make and use enough of the claimed DNA sequences to justify the scope of the generic claims. The specification of the '008 patent contained only broad statements to the effect that all analogs of EPO could be made, but with actual details for preparing only a handful, and was therefore insufficient.

DISCLOSING THE "BEST MODE" OF LIVING MATTER AND ITS PRODUCTS

All patent applicants are required to disclose the "best mode" known to them of carrying out the invention as part of the consideration for the grant of a seventeen-year monopoly.¹⁵ Applicants for patents in the field of biotechnology have an added complication in complying with that requirement. Whereas inventors of ordinary chemical products and processes can generally describe their materials and how to get them with words, and a described chemical process presumably reliably produces the same result every time it is carried out, cells cannot be made available by verbal description, and processes carried out in living systems are subject to greater variability so that a written description does not guarantee that the reader will achieve an exact replication of what the patentee got.

To solve those problems, living materials and their essential parts can be "disclosed" by depositing them in a depository which undertakes to maintain them throughout the life of the patent. While that alternative is always available to applicants, the question frequently arises whether a deposit is required in particular instances; that is, whether the disclosure is fatally deficient when a deposit is not made.

The best producer of EPO known to Amgen was a strain of Chinese hamster ovary (CHO) cells transfected with an expression vector in order to amplify expression. Amgen's expression method used selective pressure to cause a CHO cell containing the expression vector having a gene coding for resistance to a particular drug in association with the EPO gene to produce EPO protein. The '008 specification described

13. *Id.* at 28.

14. 537 F.2d 498 (C.C.P.A. 1976).

15. 35 U.S.C. § 112 (1988).

the strain of cells that were used as a starting material and both the techniques and specific drug concentrations that were used in the amplification process.

GI invited the court to require a deposit "[i]n the field of living materials such a microorganisms and cell cultures" so that the public could have access to exactly the best mode contemplated by the inventor.¹⁶ Although treating the question as one of first impression, the Federal Circuit referred to established principles and declined to create a new "best mode" requirement for biotechnology inventions. It held that Amgen had satisfied the best mode requirement by disclosing what the preferred strain was and by describing how to prepare it using standard techniques and known starting materials. Even though exact duplication of the cells used by the patentee might not be achieved, the court held that the statute does not require a guarantee that every aspect of the specification be precisely and universally reproducible.¹⁷

The "best mode" issue also came up in *Scripps Clinic & Research Foundation v. Genentech, Inc.*¹⁸ There, it concerned whether the patentee had adequately described certain monoclonal antibodies whose use was very important in the extraction of the desired protein, Factor VIII:C, from natural sources. The antibodies were obtained by the patentee by injecting mice with concentrated Factor VIII, collecting their spleen cells, fusing those cells with cancer cells to produce hybridomas, screening those hybridomas for the ability to produce the desired antibodies, and evaluating the produced antibodies for their ability to bind Factor VIII sufficiently to allow efficient extraction. This exercise, which the court described as "laborious," resulted in the production and identification of a specific antibody called "2.2.9" that worked admirably well for the purification.¹⁹

The patent described in detail all of the manipulations that led to "2.2.9," but no deposit was made of the antibody or of the hybridoma that produced it. Although a deposit would have avoided considerable effort and uncertainty for one who wished to practice the claimed invention, the court found such a deposit was so clearly unnecessary that it reversed the trial court's entry of summary judgment of invalidity for failure to disclose the best mode and directed entry of summary judgment for the patentee on that issue.²⁰

THE SCOPE AND MEANING OF CLAIMS

Scripps was a consolidated appeal of four district court cases between Scripps Clinic and Research Foundation and Genentech, Inc.²¹

16. *Amgen*, slip op. at 20.

17. *Id.* at 25.

18. Nos. 89-1541, -1542, -1543, -1646, -1647 (Fed. Cir. Mar. 11, 1991).

19. *Id.* at 28.

20. *Id.* at 30. This aspect of the *Scripps* decision, as well as others, is now the subject of a petition for rehearing *en banc*.

21. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 666 F. Supp. 1379 (N.D. Cal. 1987), *modified on reconsideration*, 678 F. Supp. 1429 (N.D. Cal. 1988); *Scripps Clinic &*

The proceedings involved a number of motions for summary judgment of patent validity and enforceability, infringement, inducement to infringe, and reissue law and practice, each of which could be the basis for a full review article. For present purposes, the point of greatest interest is the Federal Circuit's treatment of issues of infringement and claim scope.

As discussed in the main article,²² Scripps accused Genentech of infringing the Scripps claims directed to Factor VIII:C, a blood clotting factor. The claims in suit were product-by-process claims and product claims. Scripps made the invention by isolating the protein from a natural source, blood plasma. Genentech was accused of infringing because it produced Factor VIII by recombinant means. The question was whether a patent claim obtained on the basis of isolating and purifying the natural protein was infringed by the same protein when produced by recombinant means. Genentech argued infringement should not be found for two reasons: (i) the process of manufacture should be read into the claims as an implicit limitation; and (ii) the recombinant product was so far changed in principle that it was non-infringing under the "reverse doctrine of equivalents." The trial court found no triable issue of fact under either of those theories and granted summary judgment that the recombinant product infringed the claims.²³

The Federal Circuit also refused to construe the claims to include the inherent process limitation proposed by Genentech.²⁴ As a matter of simple literal construction, the recombinant product was not excluded.

The court, however, found that Genentech's invocation of the "reverse doctrine of equivalents" raised contested issues of fact that precluded summary judgment. The doctrine exists "to prevent unwarranted extension of the claims beyond a fair scope of the patentee's invention," and to avoid infringement when the accused product is "so far changed in principle from a patented article that it performs the same or similar function in a substantially different way."²⁵ Issues of fact existed because "[a]pplication of the doctrine requires that facts specific to the accused device be determined and weighed against the equitable scope of the claims, which in turn is determined in light of the specification, the prosecution history, and the prior art."²⁶

The only evidence in the record cited by the court as showing differences between Factor VIII:C products derived from plasma recovery

Research Found. v. Genentech, Inc., 707 F. Supp. 1547 (N.D. Cal. 1989); Scripps Clinic & Research Found. v. Genentech Inc., 724 F. Supp. 690 (N.D. Cal. 1989), *aff'd in part, rev'd in part, vacated in part*, Scripps Clinic & Research Found. v. Genentech, Inc., Nos. 89-1541, -1542, -1543, -1646, -1647 (Fed. Cir. Mar. 11, 1991) (LEXIS, Genfed library, U.S. App. file 3925).

22. See *supra* text accompanying notes 81-93.

23. *Scripps*, 666 F. Supp. at 1390, 1394.

24. *Scripps*, slip. op. at 32.

25. *Id.* at 32-33 (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)).

26. *Id.* at 33.

and recombinant techniques related to purity levels and specific activities (which is another way of expressing purity), and conclusory testimony that the products were "apples and oranges."²⁷ This rationale, which seems to put biotechnology inventions into a special category, is troubling. To our knowledge, no one has ever successfully argued that a patent claim to ordinary chemical compound *X* is not infringed merely because the accused infringer makes it in a purity superior to what can be achieved using the process described in the patent. On the contrary, it is generally recognized that purity differences do not avoid infringement.²⁸ Of course, the court did not say that application of the "reverse doctrine" *will* lead to a finding of non-infringement, but only that there is an issue of fact to be resolved. Even so, it is questionable whether the same result would have been reached if the invention had been one of conventional chemistry and, if it would not, whether the decision reflects a sound distinction between those technologies.

The final point of interest in the *Scripps* decision is its treatment of "product-by-process" claims. The *Scripps* patent has a number of claims in which a product is claimed but is defined in terms of the process used to produce it, that process being extraction from plasma by a series of defined steps. Genentech did not practice plasma extraction, and the trial court refused to grant summary judgment with respect to those claims, reasoning that there could be no infringement unless the recited process were practiced.²⁹

The Federal Circuit disagreed with that analysis. Relying on statements from decisions dealing with the inability of process limitations to render a claim patentable over a disclosure of the same product in the prior art, the court said:

In determining patentability we construe the product as not limited by the process stated in the claims. Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product[s] prepared by the process set forth in the claims.³⁰

No authority was cited for that proposition.

While there is little precedent on this issue, we have found none that directly holds what the Federal Circuit characterized as "the correct reading of product-by-process claims."³¹ The Federal Circuit made no comment on the applicability of the Supreme Court decision in *Cochran v. Badische Anilin & Soda Fabrik*,³² on which the district court relied as support for its conclusion that "[a] product-by-process claim is infringed only by a product produced by following the same process described in

27. *Id.*

28. *Merck v. Chase*, 273 F. Supp. 68, 82 (D.N.J. 1967).

29. *Scripps*, 666 F. Supp. at 1388-89, *as modified*, 678 F. Supp. at 1433.

30. *Id.* at 39-40.

31. *Id.* at 39.

32. 111 U.S. 293 (1884).

the claim."³³

Moreover, it is doubtful whether the patentability decisions on which the Federal Circuit relied support the concept of invariable symmetry. The Court of Customs and Patent Appeals, the predecessor court of the Federal Circuit, held in *In re Moeller*³⁴ that where an inventor can only claim his invention as a product by process, he is limited in his protection to articles produced by the method recited in the claims.³⁵

If the *Scripps* decision withstands the challenges of the petitions for rehearing, it will have a major impact on the scope of patent rights obtainable by those who isolate proteins from natural sources. In a sense, the decision reflects two antagonistic results, by creating possible process-related exceptions to infringement of a product claim that, on its face, makes no reference to any process parameters, but reading process limitations out of a claim that expressly recites them.

33. *Scripps*, 666 F. Supp. at 1386-87.

34. 117 F.2d 565, 568 (C.C.P.A. 1941).

35. See also *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.").